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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,047	01/14/2004	Heinrich Kladders	01-1449	4842
28501	7590	10/27/2009	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM USA CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			DOUGLAS, STEVEN O	
			ART UNIT	PAPER NUMBER
			3771	
			NOTIFICATION DATE	DELIVERY MODE
			10/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary

Application No.

10/757,047

Applicant(s)

KLADDERS ET AL.

Examiner

/Steven O. Douglas/

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(c) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(c) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,4-13,16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohki et al. (US 5,715,811).

The Ohki et al. reference discloses an inhaler apparatus (see FIG. 8) that works based on the Bernoulli effect or principle (i.e. venturi effect) including an upper chamber (proximate reference numeral 1 in FIG. 8) and a lower housing part 6 with a capsule chamber (proximate

reference numeral 7 in FIG. 8) having a cutting device 14 with spikes 16 and air inlet openings 8 and air outlet openings 8C to conduct a powder composition contained within capsule 17. The capsule 17 (see FIG. 8 and FIG. 7) appears to be a symmetrical capsule made up of two parts telescopically pushed together (i.e. such capsules are conventionally made up of two parts telescopically pushed together leaving an associated seam) and the fine structures of any seam or elements of the capsule appear to be smaller than 0.1 mm and/or angles of taper up to 5 degrees (i.e. these are conditions met by a simple capsule that is manufactured within close tolerances).

Claims 1,4-16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hochrainer et al. (US 5,947,118).

The Hochrainer et al. reference discloses an inhaler apparatus (see FIG. 6) that works based on the Bernoulli effect or principle (i.e. venturi effect) comprising a cup shaped lower part open at (6) hinged to cap 15, a plate 8, a button 10 movable counter to a spring 11 and including spikes (unlabeled in FIG. 6). The inhaler apparatus further includes a capsule chamber accommodating a capsule (unlabeled in FIG. 6) and a magazine with a plurality of chambers 1 shown on plate 8. The capsule (see FIG. 6) appears to be a symmetrical capsule made up of two parts telescopically pushed together (i.e. such capsules are conventionally made up of two parts telescopically pushed together leaving an associated seam) and the fine structures of any seam or elements of the capsule appear to be smaller than 0.1 mm and/or angles of taper up to 5 degrees (i.e. these are conditions met by a simple capsule that is manufactured within close tolerances).

If Applicant takes issue over the capsule being manufactured within close tolerances such that elements formed on the capsule surface which are smaller than 0.1 mm and/or angles of taper up to 5 degrees, the seam being offset from center 0 to 12% of an outer longitudinal length of the capsule, or a tolerance and inaccuracy deviating from the symmetry of up to 0.15 mm in each case, Examiner has included an alternative rejection below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-13,16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki et al. (US 5,715,811).

The Ohki et al. reference discloses an inhaler apparatus (see FIG. 8) that works based on the Bernoulli effect or principle (i.e. venturi effect) including an upper chamber (proximate reference numeral 1 in FIG. 8) and a lower housing part 6 with a capsule chamber (proximate reference numeral 7 in FIG. 8) having a cutting device 14 with spikes 16 and air inlet openings 8 and air outlet openings 8C to conduct a powder composition contained within capsule 17. The capsule 17 (see FIG.8 and FIG. 7) appears to be a symmetrical capsule made up of two parts telescopically pushed together (i.e. such capsules are conventionally made up of two parts telescopically pushed together leaving an associated seam) and the fine structures of any seam or

elements of the capsule appear to be smaller than 0.1 mm and/or angles of taper up to 5 degrees (i.e. these are conditions met by a simple capsule that is manufactured within close tolerances). However, the Ohki et al. reference fails to explicitly disclose *the capsule being manufactured within close tolerances such that elements formed on the capsule surface which are smaller than 0.1 mm and/or angles of taper up to 5 degrees, the seam being offset from center 0 to 12% of an outer longitudinal length of the capsule, or a tolerance and inaccuracy deviating from the symmetry of up to 0.15 mm in each case*. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have *the capsule being manufactured within close tolerances such that elements formed on the capsule surface which are smaller than 0.1 mm and/or angles of taper up to 5 degrees, the seam being offset from center 0 to 12% of an outer longitudinal length of the capsule, or a tolerance and inaccuracy deviating from the symmetry of up to 0.15 mm in each case*, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233*.

Claims 1,4-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (US 5,947,118).

The Hochrainer et al. reference discloses an inhaler apparatus (see FIG. 6) that works based on the Bernoulli effect or principle (i.e. venturi effect) comprising a cup shaped lower part open at (6) hinged to cap 15, a plate 8, a button 10 movable counter to a spring 11 and including spikes (unlabeled in FIG. 6). The inhaler apparatus further includes a capsule chamber

accommodating a capsule (unlabeled in FIG. 6) and a magazine with a plurality of chambers 1 shown on plate 8. The capsule (see FIG. 6) appears to be a symmetrical capsule made up of two parts telescopically pushed together (i.e. such capsules are conventionally made up of two parts telescopically pushed together leaving an associated seam) and the fine structures of any seam or elements of the capsule appear to be smaller than 0.1 mm and/or angles of taper up to 5 degrees (i.e. these are conditions met by a simple capsule that is manufactured within close tolerances). However, the Hochrainer et al. reference fails to explicitly disclose *the capsule being manufactured within close tolerances such that elements formed on the capsule surface which are smaller than 0.1 mm and/or angles of taper up to 5 degrees, the seam being offset from center 0 to 12% of an outer longitudinal length of the capsule, or a tolerance and inaccuracy deviating from the symmetry of up to 0.15 mm in each case*. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have *the capsule being manufactured within close tolerances such that elements formed on the capsule surface which are smaller than 0.1 mm and/or angles of taper up to 5 degrees, the seam being offset from center 0 to 12% of an outer longitudinal length of the capsule, or a tolerance and inaccuracy deviating from the symmetry of up to 0.15 mm in each case*, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 7/27/09 have been fully considered but they are not persuasive.

In regard to Applicant's argument that Ohki and Hochrainer et al. do not disclose or suggest "the outer contour of the capsule is symmetrical(iii) angles of taper up to 5 degrees....." (see remarks page 2, lines 9-14 and page 3, lines 5-9), Examiner disagrees. Applicant's attention is directed to the Figures which clearly show a simple capsule manufactured within close tolerances which at least meets one required limitation of "angles of taper up to 5 degrees" (i.e. upon careful inspection of the Figures it can clearly be seen that the angles of taper are at or about zero degrees).

In regard to Applicant's argument that neither Ohki or Hochrainer et al. disclose Bernoulli type inhalers, Examiner disagrees. In order for the associated inhalers of both Ohki and Hochrainer et al. to work properly and aspirate the associated medications from their respective capsules, a venturi-type effect or pressure differential must be present in the inhalers for such aspiration to take place. Accordingly, the characteristics of such venturi-type effect or pressure differential works on the same principals that the principals of the Bernoulli effect works on.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
Art Unit 3771

SD
10/22/09